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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,335	05/10/2007	Bryan Stevon De Caux	KEIT-001/00US 307128-2001	4895
58249	7590	04/17/2008	EXAMINER	
COOLEY GODWARD KRONISH LLP			HOBBS, LISA JOE	
ATTN: Patent Group			ART UNIT	PAPER NUMBER
Suite 1100			1657	
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			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,335	DE CAUX, BRYAN STEVON	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-11, 17 and 18 is/are rejected.
- 7) Claim(s) 12-16 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09 June 2006</u> . | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 09 June 2006, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Status

Claims 1-18 are active in the case. Claims 1-18 are under examination; no claims are withdrawn as drawn to a non-elected invention.

The examiner notes that the active claims in the case are those submitted as amended sheets under Article 34 on 18 November 2005. The substitute specification, including drawings, claims and an abstract, submitted on 09 June 2006 was determined to be improper and has not been entered.

Claim Objections

Claims 14-16 are objected to under 37 CFR 1.75(c) as being in improper form because multiple dependent claims in claims 14 and 16, with claim 15 being dependent on claim 14, depend from claim 12, which is multiply dependent on claims 1-11. See MPEP § 608.01(n). Accordingly, claims 14-16 not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant intends to claim with the phrase "substantially as hereinbefore described and with reference to the examples".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orenga (US 5534415) and Rambach (US 5,716,799), in view of Sakai et al. ((1996) Biochem Biophys Acta 1308: 81-87) and Tani et al. ((1990) Appl. Microbiol. Biotechnol 34:5-9). Orenga recites a selective detection medium for the culture and the detection of yeasts of the species *Candida albicans*, comprising a nutrient base metabolized by said yeasts, a fluorogenic or chromogenic substrate capable of being hydrolyzed by an enzyme characteristic of said yeasts selected from

the group consisting of hexosaminidases, to release a marker, said substrate comprising an hexosamine-portion and a fluorogenic or chromogenic radical attached thereto by an oxygen carried by anomeric carbon, and an activator selected from the group consisting of hexosamine-containing compounds which are different from said substrate, and which do not inhibit the hydrolysis of said substrate by said enzyme (claim 1). He teaches that the carbon source is in the range of 0-10 g/L (col. 3), that the chromogenic substrates include those from the indolyl family (co.. 4), and that the media comprise phosphate and peptone (col. 3). Orenga also teaches that the medium comprises a nutrient base essential for the development of the yeasts, and activators of the hexosaminidase, with the nutrient base supplying a carbon source, such as glucose, glycerol, acetate, pyruvate, lactate, arginine, aminobutyrate, or a mixture of these components (col. 3, lines 51-55). He does not specifically teach ethanol.

Rambach teaches a method for demonstrating the presence or absence of a particular strain of microorganism in a culture medium, comprising: introducing at least one chromogen which is a substrate for an enzyme of the strain and at least one compound chosen from a carbohydrate at high concentration into the culture medium, so as to obtain, after hydrolysis of the chromogen, a derived color different from the basic color of the chromophore (claim 1). He teaches creation of the indoxyt family of chromogens (col. 2), that the media comprise peptones and phosphate (co. 2), and that standard medium is understood to mean any ordinary identification medium in which the carbohydrate has a simple function of carbon source, at very low or even zero concentrations, where it is considered that such concentrations make it possible to avoid any inducing effect which would modify the behavior of the microorganisms in an

uncontrolled manner and would induce errors in the identification of the microorganisms in question (col. 2, lines 3-9). He does not specifically teach ethanol.

Sakai et al. teach the growth of the methylotrophic yeast *Candida boidinii* to study secretory enzyme production (abstract). They teach that *C. boidinii* was grown on a glycerol/methanol or methanol-only media, with the methanol acting as the carbon source for the *Candida* (abstract). Productive levels of methanol ranged from 0.1% - 100% (section 2.5). Tani et al. teach the use of methylotrophic yeast *Candida* sp. Y-1 to study methanol as a raw material for fermentative products. They state that "methanol is one of the promising raw material[s] for fermentative products and has some advantages compared with n-paraffins" and teach medium A, which contains 30g methanol, along with phosphate, yeast extract (p. 5), and polypeptone (Table 2). They state that *Candida* sp. "Y-1 could utilize methanol as a sole carbon and energy source" but that unlike *C. boidinii*, Y-1 cannot use glycerol as a carbon source; Tani et al. grew "more than 100 isolated methanol-utilizing strains and 20 stock culture strains of methylotrophic yeasts" in this study (p. 6). Tani et al. also used 3% ethanol as a carbon source for the methylotrophic yeast and found better growth than with methanol for strain Y-1 (Table 4).

It would have been obvious for one of ordinary skill in the art, at the time the invention was made, to combine the teachings of Orenga, Rambach, Sakai et al., and Tani et al., to obtain the invention as recited. The parameters of a medium for the detection and/or identification of a *Candida* yeast comprising: a chromogen, of the indolyl family or other known chromogens, and a carbohydrate in the range of 1-5 g/L was well established in the art. Also well known was that many different chemicals can function as carbon sources, Orenga and Rambach both state a range of possible sources of carbon for the *Candida* strains to use. As well, methylotrophic

species of *Candida* were well known, including species using methanol and/or ethanol as carbon source, as shown by Sakai et al. and Tani et al. One of skill in the art would be motivated to combine the media and methods of Orenga and Rambach with the nutrient needs of the methylotrophic yeast strains, as exemplified by Sakai et al. and Tani et al., in order to detect the presence of multiple kinds of yeast contaminants. Rambach states that “the detection of microorganism[s] is very important, in particular in the food industry, in relation to water monitoring or in medicine, in view of the fact that these microorganisms may not only prove to be pathogenic agents but can also consist of against that reveal some types of contamination (col. 1, lines 8-13). One would have a reasonable expectation of success in that Orenga and Rambach both disclose that the carbon sources available and usable by the species of their detection/identification media and methods can be many and varied, which would include the alcohols known to be appropriate nutrients for methylotrophic species.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh